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Feasibility Study on the Design of a Probe for Rectal Cancer Detection

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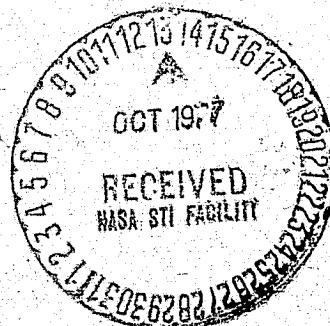
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Feasibility Study on the Design of a Probe for Rectal Cancer Detection

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April 15, 1977

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ABSTRACT

Rectal cancer mortality can be reduced if the examination technique can be improved in terms of detection capability, patient acceptance, and cost reduction. A review of existing clinical techniques and of relevant aerospace technology has included evaluation of the applicability of visual, thermal, ultrasound, and radioisotope modalities of examination. Of these, only the visual modality appears, for the present, to offer a basis for the desired improvements. The improvements would be achieved by redesigning the proctosigmoidoscope to have reduced size, additional visibility, and the capability of readily providing a color photograph of the entire rectosigmoid mucosa in a single composite view.

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SECTION I

SUMMARY

This is the final report on a brief feasibility study at the Jet Propulsion Laboratory (JPL) funded by the NASA Technology Utilization Office in the field of rectal cancer detection. The study has included a review of existing clinical examination techniques and of relevant aerospace technology. A brief summary of conclusions of the study is as follows:

- (1) Current medical theory indicates that tens of millions of proctosigmoidoscopies should be performed each year in the United States in order to reduce deaths from colorectal cancer by tens of thousands each year. By current techniques such a program is not feasible.
- (2) The current proctosigmoidoscopy procedure consists of visual examination of the rectum and sigmoid colon for the existence and growth of polyps. The procedure is costly of professional time, is uncomfortable and sometimes painful.
- (3) A need exists for a system which is acceptable to the patient, is low enough in cost to be amenable to routine screening of the asymptomatic patient by the private practitioner, provides improved detection capability and results in a permanent recorded image of the examined area.
- (4) The modalities investigated in the search for a solution included visual, thermal, ultrasound, and radioisotope. The visual modality offers the most promise.
- (5) It is recommended that development be undertaken on the visual modality, in form of an improved procto-sigmoidoscope. The improvements would consist of:
 - (a) Reduced size
 - (b) Improved visibility
 - (c) The capability of readily providing a color photograph of the entire rectosigmoid mucosa in a single composite view.

SECTION II

PROBLEM STATEMENT

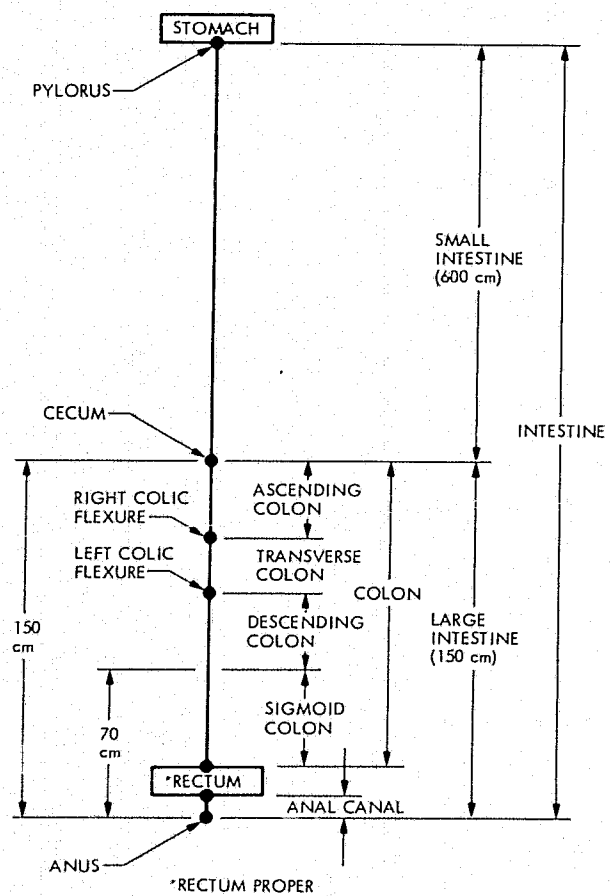
Colorectal cancer is the leading cause of death from cancer in the United States. In the typical case, the carcinoma is associated with polyps which grow out of the mucous membrane of the intestine. Roughly 50% of all polyps found in the intestine are located in the lower 25 cm of the large intestine, i.e., in the anal canal, the rectum, and part of the sigmoid colon (see Figure 2-1). Polyps of diameter larger than one cm have a high probability of malignancy.

Polyps in the rectosigmoid area can be detected by visual examination through an endoscopic instrument called the proctosigmoidoscope. The instrument is inserted through the anus, to a depth of about 25 cm and then withdrawn slowly while the physician searches for polyps.

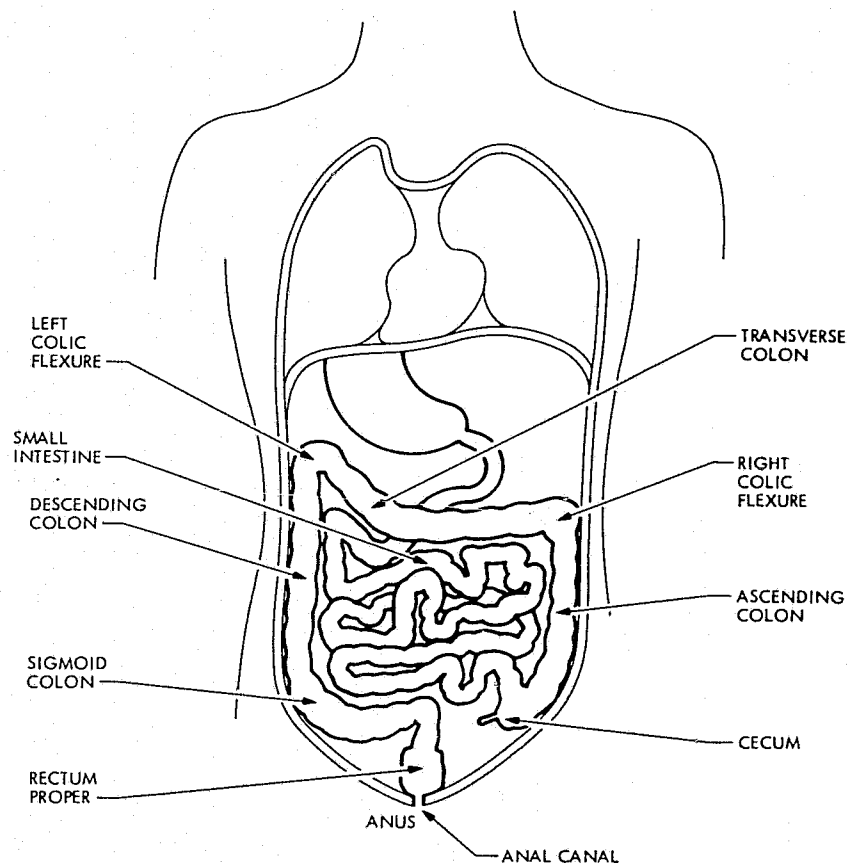
The recommended program for reduction of the incidence of colorectal cancer and for reduction of fatalities consists of periodic proctosigmoidoscopy of asymptomatic patients, particularly those over the age of 40. Removal of nonmalignant polyps while they are still small is believed to prevent the development of malignancy. Removal of malignant polyps at an early stage prevents metastasis.

Implementation of a program of prevention and cure for the susceptible population has been restricted by the incompatibility of the procedure with the demands of such a program. The principal problems are: (1) patient resistance, because the procedure is uncomfortable or painful, and (2) cost, because the procedure requires considerable physician time. Furthermore, the procedure suffers technical limitations. Specifically, visibility is limited, because of colonic folds, and there is no satisfactory means of producing a permanent image of the examined area, for follow-up correlations.

The problem then is that the potential for a significant reduction in cancer mortality is unrealizable because of the lack of the necessary detection modality.



(a) Symbolic Diagram



(b) Anatomical View From the Back

Figure 2-1. The Intestine

SECTION III

NEED

In 1974 there were 100,000 new cases of and 48,000 deaths from colorectal cancer (Reference 3-1). Over 50% of such cases are detectable by visualization of the terminal 25 cm of the large bowel; about 40% are found in the terminal 13 cm. Many researchers (e.g., Leffall, (Reference 3-1), Gilbertsen, (Reference 3-2), Rasgon, (Reference 3-3), Drexler, (Reference 3-4)) recommend routine screening of asymptomatic patients by proctosigmoidoscopy, but the economic justification is highly controversial. Bolt (Reference 3-5) has estimated a cost of \$70,000 per discovered cancer, Gilbertsen (Reference 3-2) implies a cost of about \$3000 per discovered cancer, but this is based on operation of a specialized facility capable of performing 5500 examinations per year at \$11.73 per examination (in 1972). Corman (Reference 3-6) scopes the problem by pointing out that the American Cancer Society recommends annual examinations for all patients 40 years or older and that there are 80 million (in 1975) such persons in the United States. Drexler (Reference 3-4) concludes that the cost of finding all new colorectal cancers is prohibitive; he recommends a compromise requiring one examination every 6 years in the over-50-year-old population.

Efforts have been made to induce the private physician to perform proctosigmoidoscopy. Klotz (Reference 3-7), in 1972, describes a limited procedure (15 cm depth, no preparation) with a disposable instrument. He states that every patient with diarrhea should be so examined. However, there is no evidence that his technique has been adopted generally. Powers (Reference 3-8) in a 1975 report of a test with 186 physicians in private practice considers proctosigmoidoscopy suitably within the province of the general practitioner. However, he states that the length of time required for the procedure is a major deterrent to its common use. Strode (Reference 3-9) cites the use of trained technicians to reduce cost, but this is in a clinical setting.

The inference is clear that there is no system available which is amenable to routine screening for colorectal cancer, and further, that if such a system were available it would be in widespread use.

SECTION IV

BACKGROUND

In late August 1976, a group of scientists, engineers and a physician convened at the Jet Propulsion Laboratory to discuss the feasibility of improving the design of instrumentation used for rectal examinations.

The group consisted of:

Consultants

H. Worth Boyce, M.D., Chief, Section of Gastroenterology,
University of South Florida, College of Medicine,
Tampa, Florida

John H. Reid, Ph.D., Assistant Director, Institute of Applied
Physiology and Medicine, Seattle, Washington

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Kenneth Castleman, Ph.D.

Robert E. Frazer

Richard C. Heyser

Dennis H. Le Croisette, Ph.D.

Douglas O'Handley, Ph.D.

Robert Selzer

After a review of the existing state of the field by Dr. Boyce, the remainder of the two-day meeting was spent discussing the possibilities of improving the present procedures. It was generally agreed that methods should be sought for (1) improving detectability of polyps, (2) providing a permanent record, (3) improving patient acceptability, and (4) minimizing direct physician involvement in the examination. The modalities of visual imaging, image recording, thermal mapping, ultrasound imaging, and radioisotope recording were considered. Emphasis was placed upon applying NASA technology in these fields to the alleviation of this serious medical problem.

As a result of this meeting, it was decided that JPL should study this problem in greater detail over a 6-month period with emphasis being placed on use of existing techniques in the fields of optics, thermometry, ultrasound and radioisotopes. This document is the report of the study.

SECTION V

CURRENT PRACTICE

The present method (Reference 5-1) of examining asymptomatic patients for colorectal cancer consists principally of proctosigmoidoscopy, which is a visual search for lesions in the anal canal, the rectum, and the sigmoid colon. Visualization is aided by the proctosigmoidoscope, essentially a rigid hollow cylinder, about 25 cm long by 20 mm diameter, which is inserted through the anus and the rectum and into the sigmoid colon. Typically the instrument is equipped with means for illumination and insufflation of the colonic lumen.

Physical preparation of the patient may involve cathartics, enema, and sedatives. General or local anesthesia is contraindicated because safety requires that the patient be responsive to pain. Psychological preparation consists of explanation of the details, purpose, and value of the procedure, and assurance that the procedure will be interrupted if the patient finds it excessively uncomfortable.

The procedure starts with insertion of the warmed, lubricated instrument into the anus, through the anal canal, into the rectum. The obturator (a bullet-shaped plug at the leading end) is removed by drawing it back and out through the instrument. An eyepiece is then emplaced at the proximal end of the instrument to make the channel airtight.

Further advancement of the instrument must be made only under direct vision to avoid perforation of the bowel wall. Under direct visualization the instrument is advanced, into the colon, at the necessary angle so that the lumen is always visibly in front of the leading edge. Visualization and progression may be aided by gentle insufflation; care must be taken to avoid pain caused by overdistension.

Most difficulty is encountered in attempting to negotiate the first sigmoid curve in the colon. Here the front of the instrument butts against the wall. The instrument must be angled sharply, using the sphincter as a fulcrum, to enable viewing and proceeding in the direction of the lumen. Considerable discomfort may result from distortion of the anal sphincters or from stretching of the distal colon wall. Many examinations are terminated at this point, due to patient opposition.

The instrument is inserted to its maximum depth. Then the physician starts observation for lesions, withdrawing the instrument gradually. Notes may be made of the approximate location of any

lesion by reading the depth mark on the instrument, at the anus, and by noting the quadrant of the lumen circumference in which the lesion is located. The procedure, lasting about 15 minutes, is followed by cleaning of patient and instruments.

Proctosigmoidoscopy may be performed with a rigid or flexible instrument. The rigid instruments, designated as proctosigmoidoscopes, sigmoidoscopes, or rectoscopes, are commonly about 25 cm in length, with diameters ranging from 12 mm (for children) to 29 mm with about 20 mm being a typical value.

The simplest version is a throwaway plastic tube without magnifying optics or provision for insufflation. The most complex units may include fiber optic light paths, magnifying optics, air, water, and operating channels (for biopsy or polypectomy), and means for photography.

Flexible instruments, called coloscopes (or colonoscopes), can also be used, and may be less uncomfortable for the patient. However, they are always very complex, require more training to use and are expensive (more than \$5000). Lengths range from 60 to 186 cm. Diameter is typically 15 mm, except for one pediatric version of about 9 mm. Coloscopes are used principally where indicated by symptoms or by the results of barium x-ray or hemoccult studies. They permit examination of the large bowel to the cecum.

SECTION VI

PROBLEMS

Current practice is unsatisfactory because of patient discomfort, cost, limited visibility and an inadequate record of results.

Patient discomfort results from passage of a large diameter object through the anus, distension of the colon by air, stretching of the colon wall from the force on the instrument, and distortion of the sphincters when leverage is applied to navigate the sigmoid bend. The basic difficulty arises from the practice of forcing a large, rigid, straight rod deep into a circuitous channel.

The cost of the procedure is high principally because of the amount of physician's time required. First, he must proceed cautiously to avoid risk of perforation. Second, he must be gentle and seek to minimize discomfort to retain patient cooperation. And third, he must observe carefully during the withdrawal through a 25 cm length of intestine while searching for lesions of millimeter size, possibly obscured by intestinal folds.

Visibility is inadequate because the physician can see only the forward direction. While forward visibility is needed to insure safe intubation, observation of the colon walls ideally requires lateral vision. Furthermore, forward obscuration by transverse folds in the sigmoid colon and by the rectal valves of Houston indicate the desirability of retrograde vision.

The record of the result of the examination consists of the physician's notes. If it is negative, there is no means of further corroboration. If lesions are detected, size, location and characteristics cannot be measured precisely, so there is no precise means of data correlation over a sequence of follow-up examinations.

SECTION VII

REQUIREMENTS

Regardless of modality, any improved system for examining the distal part of the large bowel for colorectal cancer should solve one or more of the previous problems without foregoing the advantages of current practice. A system solving all the problems should meet the following requirements.

The system should enable detection and location of rectosigmoid lesions at a level of cost and with a degree of facility for physician and patient which encourages its use for routine screening of asymptomatic individuals.

The equipment should be economical and rugged enough for high volume work.

The system should not introduce hazard of physical damage or morbidity due to electrical, thermal, chemical, radioactive, mechanical or any other causes.

The system should enable detection of lesions as small as 2 mm in diameter at any location on the interior walls of the anal canal, the rectal ampulla, the rectum, and the sigmoid colon, preferably to a distance of 25 cm from the anus, but at least to a distance of 13 cm (thus omitting the sigmoid colon).

The system should produce a permanent color image of the examined area, with registration of the image lesions to the real lesions.

The system should be simple enough so that the procedure can be learned readily by the general practitioner and by allied health personnel, and so that its use does not place unusual demands on the office routine, the space, and the facilities of the private practitioner.

Use of the system should not cause a degree of discomfort which discourages asymptomatic individuals from consenting to routine periodic examination.

SECTION VIII

MODALITIES

This section is a discussion of the potential of four modalities for solving the problem addressed in this report. These four modalities are (1) visual, (2) thermal, (3) ultrasound and (4) radioisotope.

Some other modalities which appear in the literature were not studied because they were not within the limited scope of this study (see Section IV, Background) and because there was no indication that they present the required solution. These modalities are (1) Occult Blood Study, (2) Barium Enema Radiology, (3) Colonic Cytology and (4) Immunology.

A. VISUAL MODALITY

Visual observation of the interior walls of the intestine is a satisfactory method of detecting rectocolonic lesions. As currently practiced, with visual access provided by the proctosigmoidoscope (see Section V), the method is deficient (see Section VI) in terms of inadequate visibility, patient discomfort, the lack of a recording of the examined area, and cost. Obviously, improvements in current instrumentation and technique which ameliorate these deficiencies while retaining the use of visual observation constitute an inherently advantageous solution to the problem addressed by this study. Possible improvements are discussed under the following headings:

- (1) The Coloscope
- (2) The Proctosigmoidoscope
- (3) Diagnosis

1. The Coloscope

The coloscope is superior to the proctosigmoidoscope in two respects. First, it permits easier, more comfortable intubation because of its small diameter, mechanical compliance, and directional control. Second, its directional control provides excellent visual coverage.

Nevertheless, this device is not commonly used for rectosigmoid examination, apparently because of its high cost and because of the greater degree of skill it requires. In practice its use does not result in reduction of the length of the examination procedure so

the patient sees no cost differential. Furthermore, while photographs of local areas can be taken readily, obtaining a composite photographic record of the entire rectosigmoid expanse would be a formidable task, partly because the flexibility exacerbates orientation problems.

Rather than attempting to improve the coloscope, it seems preferable to work on the proctosigmoidoscope. One reason is that the latter is preferred by the physician. Another is that the rigid configuration lends itself more readily to design modification. That is, it is the more convenient initial test bed, regardless of whether the ultimate design should require flexibility.

2. The Proctosigmoidoscope

Three possible improvements to this instrument which warrant investigation are (1) adding radial vision, (2) adding a panoramic camera, and (3) reducing size.

The existing instrument provides only forward vision, which is critically needed to minimize the risk of rupture of the colon during intubation, but which is incapable of seeing the far sides of some intestinal folds. Insufflation may provide more visible surface, but may also be painful. An alternate approach is to add radial vision, while retaining forward vision. The feasibility of providing such a composite viewing capability has been confirmed by preliminary design and experiment.

A second improvement which can be made is the addition of a camera which supplies a panoramic view, in a single photograph, of the inside of the intestine, from the sigmoid to the anus, seen as if the intestine were slit longitudinally and laid open.

The procedure envisioned has a technician performing intubation followed by extraction without visual examination. During extraction, done in a few seconds, the photograph is made automatically. The technician removes the (polaroid) print from the camera and hands it to the physician for analysis.

The proctosigmoidoscope must have composite-vision optics, providing both the forward and radial views. During intubation, the technician observes the forward view. During extraction the camera photographs the radial view.

Figure 8-1 is a simplified drawing of this concept. At the camera, the film is in tubular form as the analog of the intestine. At a given instant of time the optics in the camera supply an annular image to the film, which is the analog of an annular segment of the intestine. As the proctosigmoidoscope is extracted from the body, the film tube is driven longitudinally, with the camera optics stationary, so successive annuli in the intestine are imaged sequentially on the film.

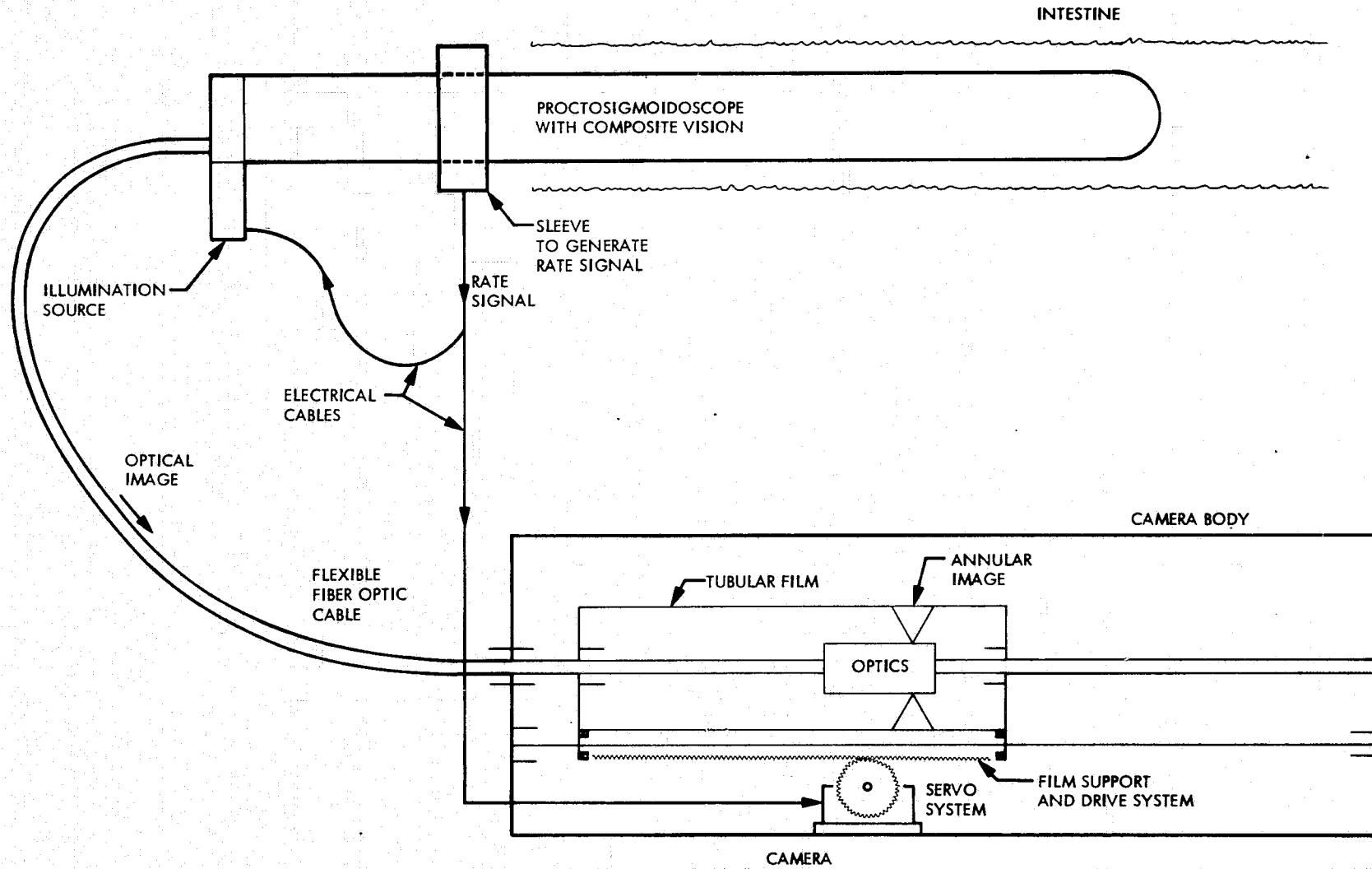


Figure 8-1. Panoramic Camera System

The two electrical cables in Figure 8-1 represent the need for two control signals, one to control illumination and the other to control the film drive, both proportional to extraction rate. Electronic measurement of extraction rate requires the presence of an artificial reference body, if it is assumed that the intestine itself will not serve for this function.

One concept of an artificial reference body, illustrated in Figure 8-1, is a short sleeve, with appropriate electrical characteristics (e.g., a linear potentiometer), fitted on the shank of the proctosigmoidoscope. The sleeve is held stationary against the exterior of the anus while the proctosigmoidoscope is withdrawn. This enables generation of the required rate signal.

An alternate concept is the use of a clear plastic sheath (with an electronic element) encasing the proctosigmoidoscope. The assembly is inserted as a unit, but the sheath is left stationary in the body during withdrawal of the proctosigmoidoscope.

Returning to the listing of three potential improvements, the third is size reduction. In effect, this improvement is already available by use of a pediatric proctosigmoidoscope, whose diameter is 12 mm, compared to the usual 21 mm. However, the existing pediatric version is extremely limited in visibility. Therefore, it is proposed that a design be attempted which incorporates the radial view concept (discussed above) into a small diameter tube.

The degree of size reduction that is beneficial depends on the desired depth of insertion. For example, one solution to the problem of enabling a high volume, low cost screening program is to limit insertion depth to 13 cm, omitting the sigmoid colon. If diameter reduction is warranted for this technique, probably 15 mm is the smallest beneficial diameter.

If an insertion depth of 25 cm (i.e., intubation of the sigmoid colon) is required, further diameter reduction may be advantageous. Probably the leading-end diameter could not be reduced because of the increased risk of perforation. However, retention of the leading-end diameter at 15 mm (in the shape of a bullet, or ball) and reducing the shank diameter may provide patient relief, because it reduces the leverage force needed at the anal sphincter.

A shank diameter reduced to 10 mm probably could not accommodate the necessary relay lens elements. If so, they could be replaced by a fiber optic cable.

A further reduction to 5 mm would not permit accommodation of fiber optics. The remaining option is to use electronic imaging, wherein the fiber optic cables (one for viewing and one for illumination) are replaced by electric wires.

Figure 8-2 is a simplified sketch of an electronic proctosigmoidoscope. Illumination is supplied by light-emitting diodes. The optical system focuses the image onto a solid state image sensor which converts the image to an electrical signal. The signal is carried by wire to an external television monitor and to an (electronic) panoramic camera. The scene on the monitor is observed during intubation. During extraction a panoramic photographic print is made.

The print can be in color if the electronic imaging sensor provides color signals. This should be possible by use of a striped filter or other spectral filters in conjunction with the part of the sensor developing the annular image.

Examination of the state of the art of solid state imaging shows that it is feasible to develop an electronic image system which will fit into the large intestine. Whether it can be made small enough to provide the desired improvement is not evident. Development of such a system would be costly.

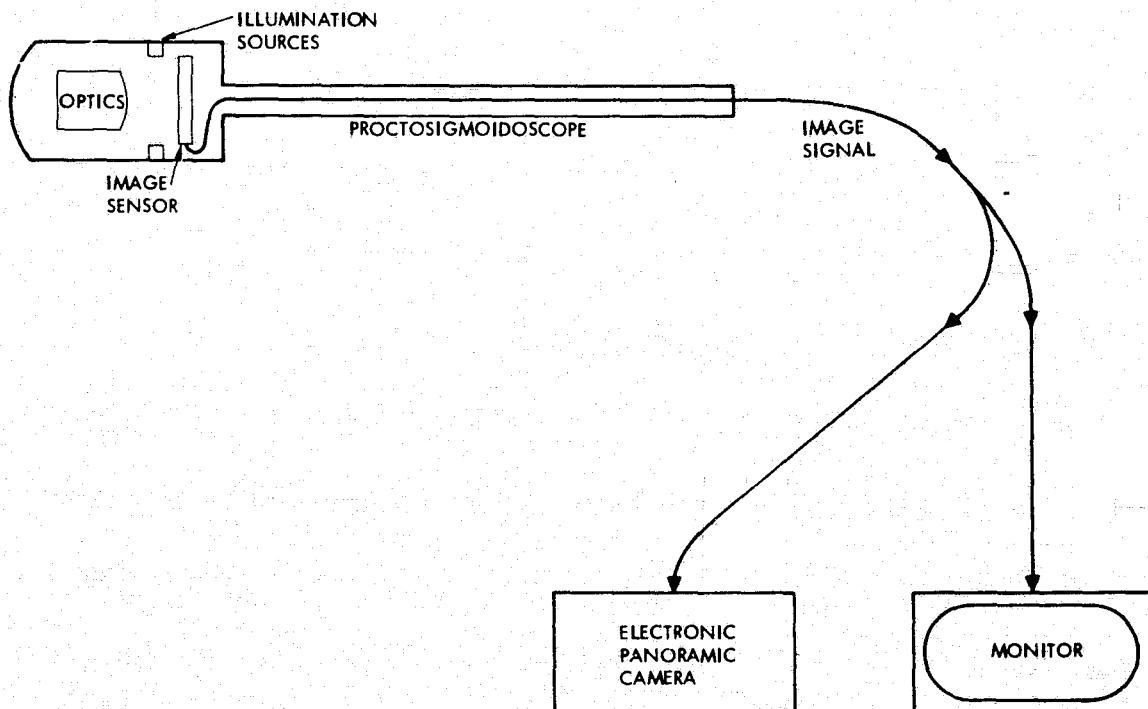


Figure 8-2. Electronic Proctosigmoidoscope

3. Diagnosis

One approach to improving detection and diagnosis of rectocolonic lesions may be the processing, analysis, and specialized display of the spectral (color) components of the image of the lesions. This technique sometimes yields information which is not visible to the eye when observing either a scene or the photographic image of a scene. The technique is based on various factors, including the increased discrimination obtainable by the use of color filters, and the increased detectability of spectral characteristics obtainable by working with ratios of spectral reflectance rather than with absolute values.

The technique has been developed and applied extensively in the aerospace field. For example, color imagery collected by the Landsat satellites in the NASA earth resources program has been specially processed to enable detection and mapping of zones, in the western United States, of chemically altered rocks which imply the existence of base metal deposits. These rock characteristics are not visible in standard color photographs.

The same technique is now being applied to the medical field. JPL, in cooperation with the Los Angeles County/University of Southern California Medical Center, is developing a system for early diagnosis of burn injury depth by the analysis of color imagery of the burned areas. This work is funded by the NASA Technology Utilization Biomedical Program.

Color photographs of rectocolonic lesions indicate the presence of both highly vascular and highly avascular characteristics. The fact that the perfusion of blood in mucosal tumors may be different from that of the surrounding lumen tissue holds the basis for the potential use of color imaging analysis for early detection and diagnosis. The analysis can be applied to color photographs or to color television images. At present, this technique is costly in equipment, so that its use would be limited to major hospitals. However, current trends in technology development (in imaging, processing, and display) offer prospects for implementing the technique at a reasonable cost in the future.

B. THERMAL MODALITY

Temperature irregularities can be expected to occur on or close to highly vascular or avascular areas on the lumen of the rectum and colon. Because of the position of this tissue within the body mass however, these differences must be small, perhaps 1°C to 2°C from the normal.

Problems associated with internal temperature measurements such as these would arise from the thermal disturbance caused by the insertion of the endoscope and its illumination source, and by the possible increased evaporative cooling of the internal surfaces.

Two methodologies could be used to monitor internal temperatures. The more simple method would utilize a thermistor or thermocouple which could be selectively placed on the surface of interest while visualizing the interior structure through the endoscope. In this method the endoscope would be modified to accept a cannula similar to those used for cardiac catheterization. Temperature resolution for this methodology would be $\pm 0.01^{\circ}\text{C}$ relative.

A second method could utilize thermal imaging techniques similar to those used in thermography. This technique would require a major change in endoscope materials to permit the transmission of the thermal infrared wavelength. This approach would be quite complex and expensive but would allow thermal scene analysis. Temperature resolution for this methodology would be $\pm 0.1^{\circ}\text{C}$ relative.

In an alternate embodiment, several thermal sensors would be arranged on a circumference of the probe such that they could simultaneously contact a circumference of the intestine. This array would permit direct measurement of relative temperature, would probably be more rapid and more accurate.

If successful, these methodologies would add a dimension to the data on rectocolonic lesions. However, it does not appear that they provide an avenue to meeting the requirements for a system amenable to routine screening of asymptomatic individuals.

C. ULTRASOUND MODALITY

The use of ultrasonic imaging for diagnostic purposes in medicine is expanding rapidly and consideration has been given to its use in rectal scanning. Diagnostic ultrasound instruments operate by sending out an acoustic signal in the 1- to 20-MHz range of frequencies and electronically processing the received signal to give information, usually in the form of a tomographic image, of the soft tissue in front of the transducer. The image is formed because ultrasonic energy is reflected at each boundary between different types of tissue and the high sensitivity of the electronic equipment allows the interfaces to be detected and plotted on the screen. The most used ultrasound device is known as a B-scan system where the term indicates that the spot on the screen is brightened according to the energy received back from the tissue boundary.

Because of the success of noninvasive B-scan systems in imaging various points of the body, the possibility of imaging the large intestine was considered. This is not practical using current equipment for two reasons: (1) the presence of air and gas in the intestine will cause a loss of information in the image, and (2) the resolution obtainable from extracorporeal scanning is poor and the minimum size of lesion detectable under any condition is probably much in excess of 1 cm.

A few attempts have been made to image the large intestine by using an instrument which is inserted into the rectum and passed up the lower bowel. An early gastrointestinal echoscope was devised by J. J. Wild and J. M. Reid in 1957 (Reference 8-1). This utilized a small acoustical head which could rotate through 360° at the end of a flexible drive source. A 360° PPI-type presentation was obtained on a cathode ray tube.

Grumman Health Systems are currently distributing a Japanese-built (Aloka) ultrasound probe for rectal scanning. This is a rigid unit that is currently undergoing clinical trials. Watanabe (Reference 8-2) has used a similar device for measuring the size of the prostate by trans-rectal ultrasound. There is no accepted commercial unit for detecting polyps in the rectum or sigmoid colon by ultrasound.

In addition to its function of imaging, ultrasound is theoretically capable of the detection of diseased tissue, by virtue of the ultrasound response of such tissue. That is, the changes in the ultrasound signal caused by transmission through diseased tissue may be measurable and ascribable to the tissue pathology. Various investigators are studying this concept. It should prove basically practical, it should be applied to investigation of aberrations in the rectocolonic region.

The design of an ultrasound unit for proctoscopy is just about within the state of the art of ultrasound diagnosis at the present time. A resolution of about 3 mm could be obtained with a miniaturized phased array system of dimensions about 5 mm long and 2 to 3 mm wide. This system could be devised using existing techniques and could fit into an existing proctosigmoidoscope. This development program is not suggested at the present time since it would result in a somewhat complex instrument.

D. RADIOISOTOPE MODALITY

Radioisotopes have been used for imaging in the body for many years. Most of the radiopharmaceuticals tend to localize nonspecifically in areas of altered vascular permeability, such as sites of inflammation or vascular congestion. One of the most useful techniques involves Technetium-99m which was introduced by Harper (Reference 8-3) and others in the early 1960s. In the soluble pertechnetate form (TcO_4), this isotope has been used for the purpose of localization in many organs including the thyroid, stomach, liver and the colon (Reference 8-4).

Only a few attempts have been made to image the lower bowel region. At the present time, there is no clear understanding of the partition of activity between the colon wall and the colon contents. For example, a normal patient was scanned 24 hr after intravenous administration of 10 mCi of Tc-99m pertechnetate for the purpose of a brain scan. The imaged activity was found to extend from the proximal cecum through the large intestine as far as the rectosigmoid; the rectum was not visualized, nor was the small intestine.

Other patients with ulcerative colitis have undergone similar scanning procedures and, although definitive results were not claimed at the time of the investigation, it does appear that scanning of the colon with Tc-99m pertechnetate may have some value in distinguishing involved from uninvolved colon in patients with ulcerative colitis. Similarly, given some similarity between the physiology of the ulcerated colon and colonic polyps, this technique may enable detection of the polyps. However, this capability has not been demonstrated, so there is no basis for assessing its applicability to the problem being addressed here.

The distribution of technetium compounds in the body is normally detected by placing a scanning device consisting of an activated sodium iodide crystal, a photomultiplier tube, photoemissive surface and associated electronics over the region of interest. If the method can be used, it has the implicit advantages of negligible discomfort to the patient and of the generation of a permanent record of radionuclide distribution. However, it has serious disadvantages of hazard and cost.

The use of an intravenously applied radionuclide for imaging internal structures carries with it an inherent hazard associated with the biological effects of ionizing radiation. Some of these effects may be short term and transient, and others may be long term and irreversible. The radiation dose to the colon during these procedures is greater than to any other organ of the body, and is estimated to be between 2.5 and 3.0 rads following oral administration, and between 1.5 and 2.0 rads following intravenous administration (Reference 8-5), when the administered amount is 10 mCi. It is for these reasons that radionuclide scanning is almost never used as a routine screening agent for diagnostic purposes.

The cost of implementing the technique is high because of the need for sophisticated instruments, a dedicated facility, and specially trained personnel. Furthermore, the procedure is complicated by an indeterminate waiting time (30 min to several hours) for distribution of the radiopharmaceutical in the region of interest.

In summary, there is no documented basis for believing that the radioisotope modality may be usable in the detection of rectocolonic lesions and, even if successful, it would introduce unacceptable risk and cost.

SECTION IX

CONCLUSIONS

Of the modalities considered for proctosigmoidoscopy, none but the visual modality appears likely to bring improvements in the foreseeable future.

The radioisotope modality seems quite inapplicable. There is little basis for believing that it would enable detection of lesions. In any case, it is precluded by risk and cost.

The thermal modality might be functionally successful. It could contribute to detection or diagnosis. However, it could not be used without an endoscope, so it does not offer a solution to the problem investigated.

The ultrasound modality may also, after suitable development, be functionally successful. The advantages are limited if an endoscope is required for intubation of an ultrasound sensor. The most attractive aspect of ultrasound is its use in the noninvasive mode. However, the performance required is currently beyond the state of the art. Also, the ultrasound system would be expensive.

The visual modality is the most attractive to pursue because it is already at an impressive state of development. Furthermore, there seem to be ways to attack all of its limitations; that is, visibility, patient discomfort, the lack of a recorded image, and cost. Visibility can be improved via optical design, by the addition of a radial view. Discomfort may be reduced by mechanical redesign, based on miniaturization possibilities, or possibly by using electronic imaging. A useful image record seems achievable by one or more means. The cost of the procedure would be reduced by virtue of improvements in visibility and in patient comfort, although the initial cost of the equipment would be higher than that of the simple instruments in use today.

No evidence has been seen to indicate that medical equipment manufacturers are addressing the problem of providing a system which would enable mass screening of asymptomatic patients. If an experimental system could be developed and demonstrated, the manufacturers could be expected to proceed with product development because of the large potential market. Therefore, the development of such a system offers an attractive opportunity for transfer of NASA technology to civilian applications.

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